FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., et al..,	**Hon. Dennis M. Cavanaugh**
Plaintiffs,	**OPINION**
v.	Civil Action No. 08-1331 (DMC)(JAD)
TEVA PHARMACEUTICALS USA, INC. et al.,	
Defendants.	

PFIZER, INC. et al.,	
Plaintiffs,	
v.	Civil Action No. 08-2137 (DMC)(JAD)
IMPAX LABORATORIES, INC.,	
Defendants.	

PFIZER, INC. et al.,	
Plaintiffs,	
v.	Civil Action No. 10-3246 (DMC)(JAD)
MYLAN INC. and MYLAN	

PHARMACEUTICALS INC.,

Defendants.

PFIZER INC. et al.,

Plaintiffs,

v.

SANDOZ, INC.,

Defendants.

Civil Action No. 10-3250 (DMC)(JAD)

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court by request of Pfizer Inc. ("Plaintiffs") and Impax Laboratories, Inc. ("Impax"), Mylan Inc. and Mylan Pharmaceuticals, Inc. ("Mylan"), and Sandoz Inc. ("Sandoz") (collectively "Defendants") for a claim construction hearing, pursuant to Local Patent Rule 4.5. The parties sought the Court's interpretation of disputed terms in U.S. Patent No. 6,630,162 (the "'162 patent") and U.S. Patent No. 6,770,295 (the "'295 patent") (collectively the "patents-in-suit").[1] A Markman hearing was held on February 14, 2012, at which all parties ably presented sophisticated and intelligent arguments. Having considered the parties' written and oral arguments, the Court has set forth its construction of the disputed terms.

I. BACKGROUND

The patents-in-suit claim controlled release formulations and methods of administering the

[1] Plaintiffs additional claim infringement of U.S. Patent No. 5,382,600 (the "'600 Patent), but there are no claim construction issues with respect to that patent.

previously known pharmaceutical compound tolterodine. Tolterodine provides a treatment for overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Tolderodine had previously been administered twice daily in the formulation entitled "Detrol." The patents-in-suit relate to a new, controlled release formulation entitled "Detrol LA."

Defendants each filed Abbreviated New Drug Application ("ANDA") forms with the U.S. Food and Drug Administration seeking to market generic versions of Detrol LA. Pfizer subsequently filed suit against Defendants for infringement of claims 1 through 18 and 20 through 23 of the '162 patent, and claims 5, 13, 16, and 17 of the '295 patent. The parties now seek construction of certain claim terms. While there are eighteen different claim terms in dispute, many of these claim terms present the same or similar issues. Thus, there are only four primary issues for the Court to consider. These issues are: (1) how to construe terms related to pharmacokinetic properties; (2) whether "Tolterodine-Related Compound(s)" and "Active Moiety or Moieties" should include the term "prodrugs;" (3) how to construe "About;" and (4) how to construe "Reduced Undesirable Side Effects."

II. LEGAL STANDARD

Claim construction is a matter of law to be determined solely by the court. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005), cert. denied, 546 U.S. 1170 (2006). Analysis of a patent infringement claim is a two-step process. Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002). A court must first construe the meaning and scope of the patent claims, Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), and then compare the claims as construed to the alleged infringing product. Tate, 279 F.3d at 1365. At this stage, the Court will only engage in the first step.

To construe the terms of a patent, a court should look first to the language of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Terms within a claim "are generally given their ordinary and customary meaning." Id. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.

To determine how a person of skill in the art would understand a patent's claim language, a court must first examine the intrinsic record–the patent itself, including the claims, the specification and the prosecution history. Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. Indeed, the Federal Circuit has explained that the specification is "usually . . . dispositive . . . [and is the] best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582) (internal quotations omitted). It is proper for a court to "rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

A patent's prosecution history is also a critical source of guidance, as it "provides evidence of how the [Patent Trademark Office] and the inventor understood the patent." Id. The prosecution history is the complete record of the proceedings before the PTO, and "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. The Federal Circuit has repeatedly emphasized the need to consult the prosecution history to "exclude any interpretation that was disclaimed during prosecution." See

Rhodia Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005) (recognizing that, in exchanges with the PTO, a patent applicant may disavow or disclaim certain claim coverage, thereby precluding any claim interpretation that would encompass the disavowed or disclaimed subject matter).

After consulting intrinsic evidence, a district court may also examine extrinsic evidence—i.e., "all evidence external to the patent and prosecution history." Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317-18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. Markman, 52 F.3d at 980. However, extrinsic evidence is generally "less significant than the intrinsic record in determining the legally operative meaning of claim language." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). Extrinsic evidence, when relied upon, must be considered in view of the specification and prosecution history. Phillips, 415 F.3d at 1320. ("[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of intrinsic evidence.").

III. DISCUSSION

A. Pharmacokinetic Claim Terms

i. Substantially Constant Serum Level

Each party argues that their respective definition of "substantially constant serum level" is derived directly from the definition provided in the specifications of the patents-in-suit.

Pfizer advances the following definition as it appears in the patents-in-suit[2]:

[2]In the '295 patent, "means" is followed by "the release profile of the controlled release formulation should essentially not exhibit any peak values."

> The term "substantially constant" with respect to the serum level of active moiety or moieties means that the serum profile after administration of the controlled release formulation does essentially not exhibit any substantial peak values. This may, more sophistically, also be expressed by reference to the "flucuation [sic] index" (emphasis added)

See '162 patent, col. 3 ll.20-25. Pfizer further explains that the "peak values" referred to within the definition are those that result from the administration of an immediate release formulation to which the instant invention is compared. Such "peak values" are claimed to be eliminated with the administration of the constant release formulation of the present invention, which accordingly achieves a "substantially constant serum concentration."[3] The "fluctuation index" referred to is explained to be a mathematical expression of the relative "flatness" of a given serum profile that sufficiently "eliminates" the peaks exhibited by the immediate release formulation.[4] The patent further specifies that the fluctuation index of the claimed invention should be no higher than 2.0.[5] (See e.g. '162 Patent, col. 3 ll.36-40).

Defendants suggest that the definition of "substantially constant serum level" should be limited to the language that immediately follows the word "means," without accounting for the fluctuation index or the repeated comparison to the immediate release formulation found throughout the remainder of the patent. Accordingly, Defendants provide that "substantially constant serum

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[3] As discussed herein, the specification further highlights the elimination of the immediate release peak levels in their relation to the side effect reduction benefit of the claimed invention.

[4]The fluctuation index indicates whether a serum level is constant, and measures the variation in a formulation's serum profile around an average serum level. The fluctuation index is calculated as $(C_{max} - C_{min})/AUCt/t$. (See '162 patent, col. 3 ll.24-35; '295 patent, col. 3 ll.11-21).

[5]Specifically, the specification provides: "the controlled release formulation should provide a mean fluctuation index . . . that is usually not higher than about 2.0."

level" should be construed to mean "the serum profile essentially does not exhibit any peak values." Defendants Mylan and Sandoz further require that the term translates to "approximately or close to flat." While Impax acknowledges that a completely flat profile is not possible as there will always be some "peak" value, Pfizer proffers that Pfizer's definition is approximately the same as that provided by Mylan and Sandoz.

The Court concludes that the construction advanced by Pfizer is supported by the claims, examples, and prosecution history of the patents-in-suit. The Court will therefore adopt Pfizer's construction.

First, the Court notes that an undeniable comparison to the immediate release formulation pervades the patents-in-suit, and the claim language should be interpreted accordingly. See Phillips, 415 F.3d at 1313 ("the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."). In addition, the patents provide illustrations of preferred embodiments which compare the serum-level-versus-time curves of an immediate release formulation and a controlled release formulation of the invention. Through such comparisons, the patentees made clear that the instant invention is intended to improve upon the prior art immediate release formulation. Accordingly, the Court concludes that "substantially constant serum level" must be defined in light of this comparison.

Next, the Court concludes that the fluctuation index must be accounted for in the definition of "substantially constant serum level." Defendants encourage the Court to ignore the fluctuation index because Pfizer presented the fluctuation index to the patent office as distinct from "substantially constant serum level." Therefore, Defendants argue that Pfizer is precluded from

adopting a construction that conflates the two terms. The Court does not agree. In addition to the fact that the patents-in-suit expressly state that the term is further defined by the fluctuation index, the patents-in-suit both include claims expressly covering formulations with fluctuation indices that are "not higher than about 2.0" or "not higher than about 1.0." Finally, the prosecution history of the patents clearly indicates that the patentees defined the controlled release formulation with reference to the fluctuation index. See, e.g. Wyss Decl., Ex. 2, Jan. 3, 2002 Response in Prosecution History of '295 Patent, p. 21-22, ECF No. 38-2 in Civ. No. 10-3246; Wyss Decl., Ex. 5, Mar. 19, 2002 Reply Under 36 C.F.R. § 1.111 in Prosecution History of '162 Patent, ECF No. 38-2 in Civ. No. 10-3246. Although the patentees did not expressly define "substantially constant serum level" with reference to the fluctuation index in the prosecution history, they repeatedly defined the controlled release formulation as providing a "mean fluctuation index of said serum level of active moiety or moieties that is not higher than about 2.0." Id. As the fluctuation index is a mathematical expression of the serum profile, it is sound to conclude that it may appropriately be used to further define the scope of "substantially constant serum level."

Contrary to Defendants' arguments, the Court finds that the patentees' inclusion of the Fluctuation Index serves to further define what must be avoided to have a "substantially constant serum level." Defendants' construction is improper, as it would call on this Court to ignore language explicitly provided by the patentees to define their invention in several of the claims of the patents-in-suit.[6] See Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1362 (Fed. Cir. 2007); see also Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (holding "[a]

[6] Reference to the fluctuation index can be found in all but one of the claims of the '162 patent and four claims of the '295 patent.

claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so"). Defendants have thus failed to adequately explain why a numeric expression of the range of fluctuation indices covered by the patents renders "substantially constant serum level" meaningless.[7]

Therefore, in light of the well-established rule that an express definition provided in the specification controls, the Court concludes that "substantially constant serum level" must be defined by reference to the immediate release formulation and with reference to the Fluctuation Index as provided in the patent. See Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1380 (Fed. Cir. 2009). The Court therefore adopts the definition of "substantially constant serum level" provided by Pfizer.

ii. Steady State Limitation[8]

Defendants suggest that all terms should be interpreted in light of a "steady state limitation" that is allegedly implied by the claimed invention. Specifically, Defendants contend that a steady state requirement is evidenced by the data provided within the patent as well as the general practice for studies conducted on similar drugs.

The Court finds that a steady state limitation is not provided for in the patent, nor is it required by the evidence highlighted by Defendants. First, Defendants have failed to produce case

[7] The Court takes note of the argument advanced by Defendants that the image provided in the patent represents measurements that were never actually taken. While Defendants argue that such misleading data counsels a rejection of the immediate release comparison, it is undeniable that the patent as a whole draws distinct comparisons to the immediate release formulation. Accordingly, this Court declines to reject the immediate release comparison on the basis of the alleged falsified data.

[8] "Steady State" occurs after multiple consecutive doses of a drug. With a "steady state" condition, the concentration of the drug in the blood at hour 24 will not return all the way to zero.

law to support the conclusion that comparisons drawn to prior art necessitates the conclusion that similar studies must have been conducted on both inventions.[9] Further, while it is true that Example One, the only example provided in the patents-in-suit, demonstrates measurements taken on day seven of the treatment period, this does not call for the conclusion that a steady state limitation is required. In fact, the Federal Circuit has specifically cautioned against limiting claims to preferred embodiments. Phillips, 415 F.3d at 1323 (the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment"). Notably, the patentees here specifically disclaimed any interpretation of Example One that might restrict the claimed invention to the preferred embodiment. As such, a steady state requirement cannot be derived from the information provided in the patents-in-suit.

The Court also notes that Defendants' reliance on the case of Geneva Pharmaceuticals is misplaced. Defendants rely on the case of Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC, to support the finding of the steady state limitation as a means to avoid the risk that a given embodiment could simultaneously infringe and not infringe the claimed invention. 349 F.3d 1373 (Fed. Cir. 2003). In Geneva Pharmaceuticals, the Federal Circuit rejected a proposed construction as "the epitome of indefiniteness" when it would allow for a given embodiment to simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis. Id. at

[9]Defendants maintain that because oxybutynin involved studies conducted over a period of more than eight weeks and demonstrated that serum concentration measurements taken at steady state differ from measurements taken after only a single dose, the instant invention must call for similar steady state measurements. Defendants also suggest that a steady state requirement is supported by the fact that other comparable studies have been conducted over periods of time ranging from eight to twelve weeks.

1384. The Court rejected the construction as "indefinite" as its "legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." Id. The Court in Geneva Pharmaceuticals, however, resolved to construe the term broadly in order to avoid potentially conflicting conclusions regarding infringement of the claimed invention. Id. Here, by contrast, Defendants encourage this Court to adopt a more narrow construction which is not explicitly provided for in the patent. This Court declines to do so and finds that Geneva Pharmaceuticals does not advise to the contrary. Moreover, Defendants have failed to demonstrate that the imposition of a steady state limitation would resolve the alleged problem. There is no direction by which the requisite steady state should be accomplished to achieve the proper measurement. As such, an undefined "steady state" requirement does not preclude the possibility that a given invention might simultaneously infringe and not infringe the claimed invention.

Finally, while the extrinsic evidence highlighted by Defendants suggests that data collected from single dose measurements may be less reliable, it does not support the conclusion that it is entirely not meaningful. First, the mere fact that an extrinsic article defined C_{min} as "observed minimum drug plasma concentration at steady state," does not mean that the term in the patents-in-suit embodies the same limitations.[10] Nor do the statements made by named inventor Dr. Olsson in her deposition testimony conclude that steady state measurements are required for the instant invention. Rather, Olsson's statements may more properly be characterized as concluding that taking measurements at steady state is the preferable procedure and that a clinical study involving the

[10]Defendants refer this Court to Skelly, et al., "In Vitro and In Vivo Testing and Correlation for Oral Controlled/Modified-Release Dosage Forms," Pharma Res. 7:975 at 981 (1990). The article is described as the report of a December 1988 workshop that was co-sponsored by FDA and various U.S. and international scientific organizations.

administration of the drug product once would not accomplish a clinically relevant C_{min}. Such statements fall well short of establishing a steady state requirement for the instant invention.[11]

Based upon the foregoing, the Court finds that the evidence highlighted by Defendants is insufficient to find an implied steady state requirement for measuring the pharmacokinetic terms. Accordingly, the Court finds that there is no steady state requirement.

iii. The Fundamental Limitation

The Court similarly declines to proclaim a "fundamental limitation" within which all claim terms should be interpreted. Defendants Mylan and Sandoz appear to argue that the fundamental limitation is a general concept expressed in each of the claims in the patents-in-suit. Therefore, Defendants suggest that the claim construction analysis should be guided accordingly, and propose the following overarching limitation within which the claim terms should be understood:

> After administration to a patient, the serum concentration profile of the unbound active moiety(ies) is approximately constant or flat and essentially does not exhibit any peak values for a period of 24 hours when measured at a steady state.

Defendants contend that such fundamental limitation was the critical basis upon which the patent examiner granted the patents-in-suit, and consequently, this Court must construe the disputed claim terms in light of this fact.[12]

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[11] Rather, such statements could equally support a construction that requires the administration of at least two doses prior to measurement. Accordingly, such statements cannot be sufficient to impose a steady state limitation that is not otherwise provided for in the patent.

[12] To support the theory that the fundamental limitation is the basis upon which the patent was approved, Defendants point to the following statement made by the Examiner in the "statement of reasons for allowance" for the '295 patent:

> The prior art does not show nor fairly suggest applicants' method of treating unstable or overactive bladder wherein a specific dosage form of tolterodine maintains a distinct substantially constant serum level for at least 24 hours. The distinct release profile enables one to maintain the desired serum profile through once daily administration while

To support the imposition of a fundamental limitation, Defendants rely on the case of O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351 (Fed. Cir. 2008). Defendants' reliance, however, is misplaced, as O2 Micro did not involve the finding of a fundamental limitation. Rather, O2 Micro found that a district court must construe a claim term when the parties agree that a claim term has a common meaning but disagree over what that plain meaning is. Id. at 1361 ("[a] determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute"). While this Court will pay due attention to the claims, specification, and prosecution histories relevant to claim construction for the patents-in-suit, it declines to impose an unprecedented overarching limitation upon the process.

iv. The Twenty Four Hour Terms

Each of the patents-in-suit contain a term that includes a twenty four hour time specification.[13] This Court sees no reason, and the parties advance no compelling argument, to construe these terms in any way other than their plain and ordinary meaning.

B. Tolterodine Related Compounds and Active Moiety or Moieties

i. Tolterodine Related Compounds

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significantly reducing side effects.
(Wyss Decl. Exh. 1 at p. 2, ECF No. 38-2). Defendants maintain that the fundamental limitation receives further support by repeated distinctions to prior art drawn by the applicants in the procedural history. The references highlighted by Defendants are statements made by the applicant's attorneys with the PTO to demonstrate that the patent teaches all of the elements and discloses every limitation of the present invention, that the claimed invention was not anticipated by the prior art, and that the prior art would not achieve the same substantially constant serum level.

[13]"The '295 patent term is "for at least 24 hours" and the '162 patent term is "for 24 hours."

The term "Tolterodine Related Compounds" appears in claims 1 through 10 and claim 20 of the '162 patent. The principle dispute between the parties is whether the term should be construed to include the language "and prodrug forms thereof." Plaintiffs' proposed construction of the term is "[t]he active metabolite of tolterodine, the corresponding (S)-enantiomer to tolterodine, the 5-hydroxymethyl metabolite of the (S)-entantiomer, and the corresponding racemate to tolterodine." Defendant's proposed construction is:

> The term 'tolterodine-related compound' is meant to encompass the major, active metabolite of tolterodine, *i.e.* (R)-N, N-diisopropyl-3-(2-hydroxy-5-hydroxymethyl-phenyl)-3-phenylpropanamine; the corresponding (S)-enantiomer to tolterodine; *i.e.* (S)-N,N-diisopropyl-3-(2-hydroxy-5-methylphenyl)-3-phenylpropanamine; the 5-hydroxymethyl metabolite of the (S)-enantiomer, *i.e.* (S)-N,N-diisopropyl-3-(2-hydroxy-5-hydroxymethylphenyl)-3-phenylpropanamine; as well as the corresponding racemate to tolterodine, *i.e.* (R,S)-N,N-diisopropyl-3-phenylpropanamine; and prodrug forms thereof.

At the outset, the Court notes that while the disputed term is in the '162 patent, Defendants' construction relies on the specification for the '295 patent. As the Federal Circuit has noted, "[t]he specification that is relevant to claim construction is the specification of the patent in which the claims reside." Young Dental Mfg. Co. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1143 (Fed. Cir. 1997).

In arguing for their own respective constructions, both parties claim that the following language from the '162 patent specification supports their position:

> The pharmaceutical formulation according to the present invention has proved to be very suitable for administering the above mentioned drug tolterodine, the chemical name of which is(R)-N, N-diisopropyl-3-(2-hydroxy-5-methylphenyl) -3-phenylpropanamine, and would likewise be suitable for its related compounds, i.e. the major, active metabolite of tolterodine, i.e. (R)-N, N-diisopropyl-3-(2-hydroxy-5-hydroxymethyl-phenyl)-3-phenylpropanamine; the corresponding (S)-enantiomer to tolterodine; *i.e.* (S)-N,N-diisopropyl-3-(2-hydroxy-5-methylphenyl)-3-phenyl propanamine; the 5-hydroxymethyl metabolite of the (S)-enantiomer, *i.e.* (S)-N,N-

> diisopropyl-3-(2-hydroxy-5-hydroxymethylphenyl)-3-phenylpropanamine; and prodrug forms and pharmacologically acceptable salts thereof.

'162 patent, col.6, ll.26-42. Plaintiffs claim that this paragraph sets forth four categories of compounds for which the pharmaceutical formulation would be suitable: (1) tolterodine, (2) tolterodine related compounds, (3) prodrugs, and (4) salts. Under this reading, the second category, "tolterodine related compounds," is itself limited to (a) the major, active metabolite of tolterodine, (b) the corresponding (S)-enantiomer to tolterodine, (c) the 5-hydroxymethyl metabolite of the (S)-enantiomer, and (d) the corresponding racemate to tolterodine. Plaintiffs thus exclude prodrugs and salts from the category of "tolterodine related compounds." Defendants, meanwhile, read this paragraph as setting forth five categories of compounds, all of which qualify as tolterodine related compounds: (1) the major, active metabolite of tolterodine; (2) the corresponding (S)-enantiomer to tolterodine; (3) the 5-hydroxymethyl metabolite of the (S)-enantiomer; (4) the corresponding racemate to tolterodine; and (5) prodrug forms and pharmacologically acceptable salts thereof.

Plaintiffs have the more compelling argument on this issue. Reading the language of the '162 patent specification to include prodrugs as a tolterodine-related compound would also necessitate reading "pharmacologically acceptable salts thereof" as a tolterodine-related compound. Such a reading would be inconsistent with the actual claims of the '162 patent. Claim 1 of the '162 patent specifically claims "[a]n oral pharmaceutical formulation containing tolterodine or a tolterodine-related compound, or a pharmaceutically acceptable salt thereof, as active ingredient . . ." This indicates that pharmaceutically acceptable salts are separate from tolterodine-related compounds. If pharmaceutically acceptable salts were considered a tolterodine-related compound, however, claim 1 would list salts twice, which would render a portion of that claim superfluous. As the Federal

Circuit has noted, "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." Merck, 395 F.3d at 1372 (Fed. Cir. 2005) (citing Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000), Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed. Cir. 1996). Plaintiffs' proposed construction is thus preferable, as it does not render portions of the claim superfluous.

Further, while many of the claims do claim salts, none of them expressly claim prodrugs. Even though prodrugs are discussed in the specification, there is no requirement that the discussion appear in the claims. See, e.g., SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) ("If everything in the specification were required to be read into the claims . . . there would be no need for claims."). For these reasons, the Court's construction of "Tolterodine Related Compounds" is "[t]he active metabolite of tolterodine, the corresponding (S)-enantiomer to tolterodine, the 5-hydroxymethyl metabolite of the (S)-entantiomer, and the corresponding racemate to tolterodine."

ii. Active Moiety or Moieties

The parties also dispute the meaning of the term "Active Moiety or Moieties," which appears in claims 1, 20, and 21 of the '162 patent, and claims 1, 3, 9, and 11 of the '295 patent. As with "tolterodine-related compounds," the principle dispute is whether "prodrugs" is included in the definition of the term. Plaintiffs' proposed construction of the term is "[t]olterodine, the active metabolite of tolterodine, the (S)-enantiomer to tolterodine, and the active metabolite of the (S)-enantiomer to tolerodine." Defendants' proposed construction is:

> By the term "active moiety or moieties" is meant the sum of free or unbound (*i.e.* not protein bound) concentrations of (i) tolterodine and active metabolite thereof, when tolterodine (or prodrug form) is administered; or (ii) tolterodine and active metabolite

> thereof and/or (S)-enantiomer to tolterodine and active metabolite thereof, when the corresponding racemate (or prodrug form) is administered; or (iii) active metabolite, when the (R)-5-hydroxymethyl metabolite of tolterodine (or prodrug form) is administered; or (iv) (S)-enantiomer to tolterodine and active metabolite thereof, when the (S)-enantiomer (or prodrug) is administered; or (v) active (S)-metabolite, when the (S)-5-hydroxymethyl metabolite is administered.

Defendants Teva and Impax contend that their construction is a verbatim copy of the express definition of "Active Moiety or Moieties" listed in both patents' specifications. Defendants Teva and Impax further contend that Plaintiffs' proposed construction is wrong not only because it ignores the express definitions, but also because it is inconsistent when read in light of the specifications. On this point, Defendants Teva and Impax note that under Plaintiffs' construction, the four compounds included (tolterodine, the active metabolite of tolterodine, the (S)-enantiomer to tolerodine, and the active metabolite of the (S)-enantiomer to tolterodine) would qualify as active moieties if they were found in the blood regardless of what drug was administered as the active ingredient. According to Defendants Teva and Impax, however, "this is not how 'Active Moiety or Moieties' is defined in the specification. Rather, whether a compound qualifies as an active moiety depends on what compound is administered as the active ingredient."

Defendants Mylan and Sandoz agree with the brief from Defendants Teva and Impax on the proposed construction for "Active Moiety or Moeities," and provide additional arguments for why this Court should reject Plaintiffs' proposed definition. First, Defendants Mylan and Sandoz argue that Plaintiffs' proposed construction eliminates the critical concept of "protein binding" from the inventors' definition. Defendants Mylan and Sandoz argue that Plaintiffs' construction would cover both protein-bound and unbound versions of the four compounds it lists, whereas the inventors expressly limited the definition to "free or unbound (i.e. not protein bound)" versions of the

compounds. Second, Defendants Mylan and Sandoz argue that Plaintiffs' proposed construction eliminates the inventor's specific description of the different ways of administration encompassed in the claimed invention.

In response to the arguments raised by Defendants Teva and Impax, Plaintiffs contend that whether prodrug forms of a compound can be administered in order to produce the "active moiety or moieties" is a non-sequitor. Plaintiffs state that whether "active moieties" can be derived from prodrugs or not does not change the definition of the term. Plaintiffs further contend, in response to Defendants Mylan and Sandoz, Defendants' proposed construction is improperly redundant, and would not give meaning to all of the claim terms. The Court finds this last argument to be the most compelling.

Pharmaceutical formulations generally contain an active ingredient that produces a response in a patient. After administration, the body metabolizes the active ingredient, altering its structure and creating altered compounds called "metabolites." Sometimes the metabolites also produce a response in the patient, in which case they are called "active metabolites." Together, the active ingredient and any active metabolites are called "active moieties."[14]

Plaintiffs note that the specifications describe compounds that can be administered through the claimed formulations as "active ingredients" (tolterodine, its related compounds, prodrug forms of each, and salts) and compounds that ultimately act on the body as active moieties (tolterodine, its active metabolite, its (S)-enantiomer, and its (S)-enantiomer's active metabolite). Defendants'

[14] It should be noted that to the extent that this background refers to extrinsic evidence, the Court may properly rely on that evidence to help understand the underlying science. See, e.g., Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1585 (Fed. Cir. 1996) ("Had the district court relied on the expert testimony and other extrinsic evidence solely to help it understand the underlying technology, we could not say the district court was in error.").

proposed construction, which describes the compounds that could be administered to produce each active moiety, is improperly redundant. As Plaintiffs correctly note, every claim in suit has a separate claim term that indicates what compounds are administered." For example, claim 1 of the '162 patent claims a "pharmaceutical formulation containing tolterodine, a tolterodine related compound, or a pharmaceutically acceptable salt thereof" as the drug administered, which produces substantially constant serum levels of "active moiety or moieties." Defendants' proposed construction would list the compounds that could be administered twice: in the administration term of the claim, and again in the "active moiety or moieties" term. Again, constructions that give meaning to all terms are preferred over those that do not. Merck, 395 F.3d at 1372. Defendants' proposed construction would thus render portions of the patents superfluous, and the Court will therefore adopt Plaintiffs' proposed construction.

C. ABOUT

The Court finds no reason to construe the term "about" other than by its ordinary meaning. Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1560-62 (Fed. Cir. 1994). The term "about" appears in several places throughout the patents-in-suit, each time in reference to the measurement of pharmacokinetic or in vitro properties. See Joint Claim Construction Statement, p. 7 - 8.[15] Defendants suggest that the term "about" should be given its plain and ordinary meaning, but that it should be construed in light of the technological facts of the case. While the Federal Circuit has found occasion to construe the term "about" in light of the technical facts of the case, such cases are limited to circumstances in which it is apparent from the claims, specification, and prosecution

[15]The term "about" is used in connection with the amount of in vitro release, the mean fluctuation index, the serum profile, and the serum level.

history that the patentees intended the word to mean something other than its ordinary meaning.[16] See Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1368 (Fed. Cir. 2008) (construing "greater than about 30 [mu] m"); Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)(construing the term "about 5:1 to about 7:1"). In fact, Courts routinely decline to add additional limitations to "about." See Merck, 395 F.3d at 1372 (Fed. Cir. 2005); Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1560-62 (Fed. Cir. 1994); UCB, Inc. v. KV Pharm. Co., No. 08-223, 2009 WL 2524519, at *6 (D. Del. Aug. 18, 2009). Here, in light of the terms' continued use to qualify different terms used in the claims of the patents-in-suit, the Court declines to undertake a specific analysis for each time the disputed term is used. Accordingly, the Court concludes that "about" should be given its plain and ordinary meaning of "approximately" or "close to."

D. REDUCED UNDESIRABLE SIDE EFFECTS

Finally, the parties dispute the meaning of the term "Reduced Undesirable Side Effects," which appears in claims 3 and 11 of the '295 patent. Plaintiffs state that the term is unambiguous and therefore requires no construction beyond its plain and ordinary meaning, which is reduced undesirable side effects. Defendants contend that the term is indefinite because it is unclear as to the amount of reduction required and whether the reduction must be to the number of side effects, to the degree of side effects, or both.

While Plaintiffs state that the term is unambiguous, they appear to provide a construction in their opening brief in which the term is construed as "reduced undesirable side effects compared to those of immediate release tolterodine." This relies on the '295 patent specification, which states

[16]The cases relied upon by Defendants involve the construction of a single claim term that included the word "about," but does not seek to construe the term "about" as it is used in various contexts throughout the patent.

that the invention, "[w]hile maintaining the desired effect . . . gives a significant reduction of the . . . side-effects, particularly dry mouth, compared with those . . . of immediate release tablets ." '295 patent, col. 2, ll. 21-24.

Defendants contend that this construction leaves some issues unsettled. Defendants take issue with the fact that the language in the specification includes the words "particularly" or "such as" immediately before the words "dry mouth." This indicates to Defendants that other side effects besides dry mouth are at issue, and that dry mouth is simply an example of those side effects. In responses, Plaintiffs cite to Wyeth v. Anchen Pharms., No. 06-386, 2007 WL 6548861 (C.D. Cal. Dec. 20, 2007) for its holding that the term "diminished incidence(s) of nausea and emesis" was not too vague for construction. Unlike Plaintiffs' construction, however, the language in the Wyeth case made it explicitly clear that only two side effects were at issue. Defendants also note that Plaintiffs' proposed construction does not appear to address whether the patent claims a reduction in the number of side effects or the degree of the side effects. Importantly, however, Plaintiffs' proposed construction does provide a clear point of comparison for the "reduced side effects," in that they are reduced in comparison to the immediate release formulation of the invention.

The construction of this term presents a similar issue as one recently addressed by the District of Delaware. In Sepracor Inc. v. Dey, L.P., the parties requested construction of the term "side effects" in a patent related to the "the optically pure R(-) isomer of albuterol to treat bronchial disorders while at the same time reducing side effects associated with the use of the raceraic mixture of albuterol." 590 F.Supp.2d 649, 651 (D.Del. 2008). There, the specification also referred to "side effects" with language "suggesting that the enumerated side effects are merely exemplary," as the references included the phrases "such as" and "for example." Id. at 656. The Sepracor Court stated

that this militated against adopting any construction that would limit "side effects" to those examples set forth in the specification. Id. Rather, the Sepracor Court reasoned that "side effects" did not require construction, since it was "not clearly technical in nature," but instead was "a general term amenable to facile understanding." Id. In so reasoning, the Sepracor Court relied on the Federal Circuit's explanation that "[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Id. (citing Phillips, 415 F.3d at 1314).

The Sepracor Court's reasoning is instructive in this matter, and its logic indicates that a finding of indefiniteness is not warranted. "Claims are considered indefinite when they are 'not amenable to construction or are insolubly ambiguous . . . . Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning.'" Young v. Lumenis, Inc., 492 F.3d 1336, 1346 (Fed. Cir. 2007) (citing Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342 (Fed. Cir. 2005)). As with the term "side effects" in Sepracor, the term "reduced undesirable side effects" at issue here is not clearly technical in nature, but rather, is a general term amenable to facile understanding. Further, as the Court has noted, the patents-in-suit feature an undeniable comparison to the immediate release formulation Detrol. A construction of the term "reduced undesirable side effects" should reflect this comparison. A person of ordinary skill in the art would therefore understand, in light of both the claims and the specification, that the term simply refers to reduced undesirable side effects compared to those of the immediate release version of tolterodine.

IV. CONCLUSION

The Court, in accordance with the discussion above, has construed the terms of the '162 and '295 Patents.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: April 12, 2012
Orig.: Clerk
cc: All Counsel of Record
Hon. Joseph A. Dickson, U.S.M.J.
File